U. S. Department of Energy

Environmental Management Consolidated Audit Program

Module 1

Checklist for General Laboratory Practices
Quality Assurance Management

Audit ID: _____

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Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.1	**Quality Assurance Documents**		
1.1.1	The laboratory has developed a Laboratory Quality Assurance Plan (QAP) consistent with DOE Order 414.1 and SW-846 that is issued and maintained as a controlled document. (*ICPT SOW Attachments B/C, Criterion 1, Program*) *(SW-846, Chapter 1, Section 2.0)*		
1.1.2	The QAP defines the laboratory's policies and its commitment to: • ethical standards; • client confidentially; • good laboratory practices; and, • client service. (*ICPT SOW Attachments B/C, Criterion 1, Program*) *(SW-846, Chapter 1, Section 1.0)*		
1.1.3	The QAP includes a listing of certifications and accreditations or a reference to the location of such a list if not part of the QAP. (*ICPT SOW Attachments B/C, Criterion 5*) *(Recommended Laboratory Practice)*		

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1.1.4	The QAP describes the: • organizational structure; • functional responsibilities; • levels of authority; and, • interfaces for those managing, performing and assessing work. (*ICPT SOW, Attachments B/C, Criterion 1*) *(SW-846, Chapter 1, Sections 2.0, 2.7)*		
1.1.5	The QAP is accessible to all laboratory personnel and they are aware of its location. (*ICPT SOW, Attachments B/C, Criterion 1*) *(SW-846, Chapter 1, Section 2.7)*		
1.1.6	The QAP includes an organizational chart showing that QA personnel: • operate independently from line management • are not directly involved with cost, schedule or production functional areas; and, • report directly to the highest level of laboratory management. (*ICPT SOW, Attachments B/C, Criterion 1*) *(SW-846, Chapter 1, Section 2.7)*		

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1.2	**Quality Assurance Management**		
1.2.1	General Quality Assurance responsibilities include: • oversight of corrective actions; • oversight of PE analysis; • report to management; • internal audits; • review of SOWs and SOPs; and, • procurement Quality Assurance. (*ICPT SOW, Attachments B/C, Criterion 3*) *(SW-846, Chapter 1, Section 2.7.5)*		

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1.2.2	A Quality Assurance Officer has been designated in writing who is empowered to: • stop unsatisfactory work; • prevent reporting results from an out of control measurement system; • initiate and monitor corrective action procedures; and, • revise, control and distribute the QAP. (*ICPT SOW, Attachments B/C, Criterion 1*) *(Recommended Laboratory Practice)*		
1.3	**Performance Evaluation Programs**		
1.3.1	The laboratory demonstrates successful participation for a minimum of one year in nationally recognized PE programs (*ICPT BOA - Attachment B&C - Selected Management Requirements - Section 2*). *(SW-846, Chapter 1, Section 2.7.1)*		
1.3.2	The laboratory documents the root cause and corrective action for failed PE samples. (*ICPT SOW, Attachments B/C, Criterion 3*) (SW-846, Chapter 1, Section 2.7.1, 2.7.4.2)		

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1.4	**Personnel Training and Qualification**		
1.4.1	The laboratory organization possesses well-defined and documented roles and responsibilities for each position. (*ICPT SOW, Attachments B/C, Criterion 1*) *(SW-846, Chapter 1, Section 2.0, 2.7)*		
1.4.2	The laboratory maintains records of indoctrination and training in the form of: • attendance sheets; • training logs; • personnel training records; and, • a description of the training and indoctrination. (*ICPT SOW, Attachments B/C, Criterion 2*) *(SW-846, Chapter 1, Section 2.7)*		

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1.4.3	Documentation is maintained indicating training in: • technical skills; • laboratory analytical methods; • QC procedures; • safety policies; • waste management practices; and, • radiation worker training. (*ICPT SOW, Attachments B/C, Criterion 2*) *(SW-846, Chapter 1, Section 2.7)*		
1.4.5	The laboratory has a written analyst proficiency evaluation policy that provides a means to gauge and document the continuing competence of experienced individuals, as well as specifying additional training and documentation practices applicable to all personnel. (*ICPT SOW, Attachments B/C, Criterion 2*) *(SW-846, Chapter 4, 8000B, Section 8.4.1 for example)* *(EPA 2185, 8.2.1)*		

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1.4.6	The following personnel criteria have been satisfied: • management has established personnel qualifications for each position; • management has established training requirements for each project person; and, • personnel qualifications should be reviewed and documented periodically. (*ICPT SOW, Attachments B/C, Criterion 2*) *(SW-846, Chapter 1, Section 2.7)*		
1.5	**Quality Control Systems**		
1.5.1	The laboratory has established a system to identify, document, correct, and prevent quality problems. (*ICPT SOW, Attachments B/C, Criterion 3*) *(SW-846, Chapter 1, Section 4.3.6, 4.3.7)*		
1.5.2	There has been documented review by management to assess the effectiveness of the quality improvement system. (*ICPT SOW, Attachments B/C, Criterion 3*) *(SW-846, Chapter, Section 2.7.5)*		

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1.5.3	The laboratory has established a Non-Conformance System to identify problems, out-of-control events and issues that are not part of scheduled assessments. (*ICPT SOW, Attachments B/C, Criterion 3*) *(SW-846, Chapter 1, Section 4.4.5)*		
1.5.4	A corrective action process has been implemented which determines: • events leading to the adverse condition; • technical activities associated with the problem; • generic implications of the problem; • extent to which similar problems have occurred; • assignment of personnel to corrective action; • documentation of corrective action plan; • effectiveness of corrective actions; • actions taken to preclude recurrence; • review of regulatory requirements; and, • client notification. (*ICPT SOW, Attachments B/C, Criterion 3*) *(SW-846, Chapter 1, Section 4.4.5)*		
1.5.5	Written procedures are in place for the notification of affected organizations regarding nonconforming items. (*ICPT SOW, Attachments B/C, Criterion 3*) *(SW-846, Chapter 1, Section 1.5.5)*		

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1.5.6	The laboratory has a system that tracks corrective actions to completion. (*ICPT SOW, Attachments B/C, Criterion 3*) *(SW-846, Chapter 1, Section 4.3.7)*		
1.6	**Documents and Records**		
1.6.1	Laboratory activities affecting quality are defined in documented instructions or procedures which are: • distributed in a controlled manner; • periodically reviewed and updated; • available to all laboratory personnel; and, • retained in the laboratory's archives. (*ICPT SOW, Attachments B/C, Criterion 4*) *(SW-846, Chapter 1, Sections 4.3.8, 4.6)* *(EPA 2185, 8.5, 2.1)*		
1.6.2	The laboratory has established a minimum frequency for		

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	review of controlled documents and procedures. (*ICPT SOW, Attachments B/C, Criterion 4*) *(SW-846, Chapter 1, Section 4.6)*		
1.6.3	Documents are retained per contract specifications. *(Recommended Laboratory Practice)*		
1.6.4	Standard Operating Procedures are in place for (but not limited to) the following areas: • Sample Management; • Reagent/Standard Preparation; • General Laboratory Techniques; • Test Methods; • Equipment Calibration and Maintenance; • Quality Control; • Corrective Action; • Data Reduction and Validation; • Reporting; • Records Management; and, • Waste Disposal. (*ICPT SOW, Attachments B/C, Special QA Requirements, Sec. G.8*) *(SW-846, Chapter 1, Section 4.3)* *(EPA 2185, 8.4.4)*		
1.6.5	A system is in place to ensure that quality records are		

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	legible, accurate, and complete, e.g., independent review of records, logbooks, etc. (*ICPT SOW, Attachments B/C, Criterion 4*) *(SW-846, Chapter 1, Section 4.6)*		
1.6.6	Corrections to documents that will become quality records are made by drawing a single line through the error, initialing and dating the error, and justifying the correction (if not self-explanatory). (*ICPT SOW, Attachments B/C, Criterion 4*) *(SW-846, Chapter 1, Section 4.6)* *(EPA 2185, 8.4.5)*		
1.6.7	The laboratory has a procedure delineating the records control system that includes: • specifications of items, data, and processes of which records are to be controlled; • requirements for the preparation, review, approval, and maintenance of records to accurately reflect completed work and to fulfill statutory requirements; • requirements and responsibilities for record transmittal distribution, change, retention, protection preservation, traceability, archival, retrieval, and disposal; • verification that records received are legible and are in agreement with the transmittal document; • requirements for access to and control of the files; • procedures for the control, and client confidentiality		

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	accountability of records removed from the storage location; • procedures for filing of supplemental information and disposing of superseded records; • storage of records in a manner approved by the organizations responsible for the records; • replacement, restoration, or substitution of lost or damaged records; and, • procedures for data correction, which include how corrections are to be made and establish who is authorized to change or correct data. *(ICPT SOW - Attachments B/C - Criterion 4)* *(SW-846, Chapter 1, Section 4.6)*		
1.6.8	The laboratory has procedures in place to validate non-standardized methods, laboratory designed/developed methods, standardized methods used outside their intended range and amplifications of standardized methods to confirm that the methods are fit for the intended use. The procedures include: • scope; • description of the type of item to be tested or calibrated; • parameters or quantities to be determined; • apparatus, equipment, reference standards and reference materials required; • environmental conditions required and any stabilization period needed; • description of the procedure, including affixing		

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	identification marks, handling, transporting, storing and preparing of items, checks to be made before the work is started, checking that the equipment is working properly and, where required, calibrating and adjusting the equipment before each use, method of recording the observations and results, any safety measures to be observed; • criteria and/or requirements for approval/rejection; • data to be recorded and method of analysis and presentation; and • uncertainty or procedure for estimating uncertainty. (*ISO 17025,Section 5.4.4 & 5.4.5* and *ICPT SOW - Attachments B/C - Criterion 5)* *(SW-846, Chapter 1, Section 4.3.4)*		
1.6.9	The laboratory has procedures for reviewing and documenting changes made to data after report preparation that ensures traceability of updates. *(ICPT SOW - Attachments B/C, Criterion 4)* *(SW-846, Chapter 1, Section 4.3.8)*		
1.6.10	Records of data and other technical information are maintained in environmentally secure controlled access storage, which shall protect the records from unauthorized access or damage. Alternatively, the laboratory stores duplicate records at a different location. *(ICPT SOW - Attachments B/C, Criterion 4)*		

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	(SW-846, Chapter 1, Section 4.3.10)		
1.7	**Work Process**		
1.7.1	The laboratory maintains: • a list of typical method detection limits. achieved for water, soil and other matrices commonly analyzed; and, • procedures for determining limits of detection and frequency of verification. *(ICPT SOW - Attachments B/C, Criterion 5)* *(SW-846, Chapter 1, Section 4.4.1)*		
1.7.2	A Standard Operating Procedure is in place for reagent and deionized water production which includes (at a minimum): • preventative maintenance of water purification equipment; • control criteria; and • corrective action process for out-of-spec water. *(ICPT SOW - Attachments B/C, Special QA Requirements, Section B.4)*		

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	(SW-846, Chapter 1, Section 4.4.3)		
1.7.3	The conductivity and/or resistivity of the water from the purification system is monitored daily and the results are recorded in a logbook. *(ICPT SOW - Attachments B/C, Special QA Requirements, Section B.4)* *(SW-846, Chapter 1, Section 5.0)*		
1.7.4	Sample glassware and containers are either designated as disposable or cleaned according to recommended procedures that are listed in the individual Analytical Master Specifications. *(ICPT SOW - Attachments B/C, Special QA Requirements, Section B.1)* *(SW-846, Chapter 1, Section 4.3.3)*		

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1.7.5	A copy of the laboratory-specific Standard Operating Procedure (SOP) for glassware is posted in the glassware cleaning area. The sample preparation areas is kept clean to avoid contamination or cross-contamination. *(ICPT SOW - Attachments B/C, Special QA Requirements, Section B.2)* *(Recommended Laboratory Practice)*		
1.7.6	A refrigerator storage blank is present for the storage of all volatile organic samples. Specific procedures for assessing the adequacy of these storage blank data and taking action for nonconforming conditions is established. The refrigerator storage blank is analyzed every 14 days when samples are being stored in the laboratory. The data from the analysis of the refrigerator storage blanks is available for review. *(ICPT SOW - Attachments B/C, Special QA Requirements, Section B.3)* *(Recommended Laboratory Practice)*		

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1.7.7	The laboratory maintains hard copy laboratory notebooks that detail: • the sample bottle preparation and analytical work, including the analyses being performed; • samples being analyzed; • procedures used; • reading taken; • calculations performed; • analytical results; and, • any observations during analysis. *(ICPT SOW - Attachments B/C, Special QA Requirements, Section G.7)* *(SW-846, Chapter 1, Section 4.6)*		
1.7.8	Standards and reference materials shall be stored separately from samples and standards protected in a controlled cabinet or refrigerator. *(ICPT SOW - Attachments B/C, Criterion 5)* *(Recommended Laboratory Practice)*		

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1.7.9	Reagent grade or higher purity chemicals are used. Reagents are checked prior to use and the supporting documentation of the checks shall be filed in a manner that can be easily retrieved. *(ICPT SOW - Attachments B/C, Criterion 5)* *(SW-846, Chapter 1, Section 5.0)*		
1.8	**Statistical Control Methods**		
1.8.1	The laboratory Quality Control manager or his/her designee periodically reviews control charts at a specified frequency for out of control conditions and initiates appropriate corrective action procedures. *(ICPT BOA - Attachment B/C - Criterion 3)* *(SW-846, Chapter 1, Sections 4.3.6, 4.4)*		
1.8.2	Control methods are accessible to the individual performing the analyses, data reviewers, and the quality assurance staff. (*ICPT BOA - Attachment B&C - Special QA Requirements - Section D*) *(SW-846, Chapter 1, Section 4.3.6)*		

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1.9	**Procurement**		
1.9.1	A process is established and implemented to control purchased items and services. This process is subject to ongoing review by management to assess its effectiveness. *(ICPT BOA - Attachment B/C - Criterion 6*) *(Recommended Laboratory Practice)*		
1.9.2	Contracted items and services that have the potential to affect the quality of analytical tests are controlled to ensure conformance with contractual requirements. Such control includes one or more of the following: • source evaluation and selection (pre-performance/pre-award survey); • source verification; • audit, and/or, • examination of items or services before use. *(ICPT SOW - Attachments B/C - Criterion 6)* *(Recommended Laboratory Practice)*		

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1.9.3	Procurement system controls makes provision for the following: • identify applicable technical and administrative requirements from this Statement of Work for contracted services and items including acceptance criteria; • the process for selecting and qualifying subcontractors; • establishing processes to ensure that qualified subcontractors continue to provide acceptable products and/or services; • accepting purchased items and/or services; • receiving and maintaining procurement records, including evidence of conformance; and, • documenting nonconforming items and services. *(ICPT SOW - Attachments B/C - Criterion 6)* *(Recommended Laboratory Practice)*		
1.9.4	When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information is forwarded to appropriate management for action. *(ICPT SOW - Attachments B/C - Criterion 6)* *(Recommended Laboratory Practice)*		

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1.10	**Internal Audit Procedures**		
1.10.1	The laboratory has established an internal audit program which includes: • independent assessments by technically qualified personnel; • maintenance of an audit schedule; • audit procedures; • standard formats for reporting findings to laboratory management; and, • methods for implementing and verifying corrective actions. *(ICPT SOW - Attachments B/C - Criteria 9 &10)* *(SW-846, Chapter 1, Sections 2.7.2, 4.5)* *(EPA 2185, 8.3.5)*		
1.10.2	Personnel conducting independent assessments have sufficient authority, access to work areas, and organizational freedom necessary to observe all activities affecting quality and to report the results of such assessments to laboratory management. *(ICPT SOW - Attachments B/C - Criterion 10)* *(SW-846, Chapter 1, Sections 2.7.2, 4.5)*		

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1.10.3	Assessment results are documented, reported to and reviewed by the level of management with authority to affect any necessary corrective actions. *(ICPT SOW - Attachments B/C - Criterion 10)* *(SW-846, Chapter 1, Section 3.3.7)* *(EPA 2185, 8.3.6)*		
1.11	**Sample Receiving**		
1.11.1	The laboratory has procedures in place to address the following: • checking sample preservation (pH), • proper containers; • preserving samples when required; • notifying clients of shipping or sample anomalies; • checking holding times and notification of lab personnel of short holding times; • use of fume hoods for opening samples and shipping containers; and, • radiation screening of samples, lab notification and labeling requirements for radioactive samples. *(ICPT SOW - Attachment 1- Section 3.1.2.2)* *(SW-846, Chapter 1, Section 4.3.1)*		
1.11.2	Sample custodians document anomalies encountered in the		

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	sample receiving process. *(ICPT SOW - Attachment 1- Section 3.1.2.2)* *(SW-846 N/A)*		
1.12	**Sample Control and Building Security**		
1.12.1	Physical or administrative controls exist to ensure that: • Chain of Custody (COC) is not broken during times that laboratory staff are present or not present, • visitor access is controlled by positive administrative controls and strict escort rules developed for all visitors; and, • the facility has controlled entrance and egress points. (*ICPT SOW - Attachments B/C - Special QA Requirements - Section F*) *(SW-846, Chapter 1, Sections 4.3.1, 4.1)*		
1.12.2	A sample receiving logbook or equivalent system is used to record the chronology of sample entry into the laboratory including time, date, customer, sample identification numbers, etc. *(ICPT SOW - Attachment 1 - Section 3.1.2.3)* *(SW-846, Chapter 1, Section 4.3.1)*		

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1.12.3	When the laboratory receives samples, an internal chain of custody procedure is initiated. *(ICPT SOW - Attachment 1 - Section 3.1.3.1.1)* *(SW-846, Chapter 1, N/A)*		
1.12.4	Internal custody is maintained until final disposition or return of the sample to the client. *(ICPT SOW - Attachment 1 - Section 3.1.3.1.1)* *(SW-846, Chapter 1, N/A)*		
1.12.5	The laboratory maintains an indexed sample storage system that facilitates sample retrieval. *(ICPT SOW - Attachment 1 - Section 3.1.4.3)* *(SW-846, Chapter 1, Section 4.3.1)*		
1.12.6	The laboratory has established, implemented and documented procedures to ensure the sample's radioactivity levels are consistent with the accompanying documentation and that Laboratory regulatory levels are not exceeded. *(ICPT SOW - Attachments B/C - special QA Requirements, Section G.5)* *(SW-846, Chapter 1, N/A)*		

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1.13	**Inspection and Acceptance Testing**		
1.13.1	The laboratory maintains a current list of available (on hand) equipment types, models, and years and a general description of the facility. (*ICPT SOW - Attachments B/C - Criterion 8)* *(SW-846, Chapter 1, Section 4.3.5)*		
1.13.2	A schedule of preventive maintenance activities is developed and the performance of preventive maintenance is documented. *ICPT SOW - Attachments B/C - Criterion 8)* *(SW-846, Chapter 1, Section 4.3.5)*		
1.13.3	Procedures are defined for ensuring that balances, refrigerators, ovens, and other laboratory equipment are accurate and that their performance is monitored and documented. *(ICPT SOW - Attachments B/C - Criterion 8)* *(SW-846, Chapter 1, Section 4.3.5)*		

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1.13.4	Balances are checked each day that they are used and are calibrated at least annually by an independent company or source. *(ICPT SOW - Attachments B/C - Criterion 8)* *(SW-846, Chapter 1, N/A)*		
1.13.5	Refrigerator temperatures shall be monitored daily. (*ICPT SOW - Attachments B/C - Criterion 8)* *(SW-846, Chapter 1, Section 4.3.1)*		
1.14	**LIMS – If NOT Module 5 Audited**		Leave blank if Module 5 is completed
1.14.1	System backups occur on a regular and published schedule and can be performed by more than one person within an organization. *(EPA 2185, 8.6)*		
1.14.2	Computer programs (software) used for instrument performance out put, data reduction, and/or for data interpretation shall be validated before use and verified on a regular basis.		

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	(SW-846, Chapter 1, Section 4.4.6)		